## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re A	application of:	)	
RUDO	DLF-GIESBERT ALKEN	)	
Serial No.: 10/539,793			Group Art Unit: Unknown
Filed:	December 18, 2003	)	Examiner: Unknown
For:	USE OF L-DOPA, DERIVATIVES THEREOF AND MEDICAMENTS COMPRISING SAID COMPOUNDS FOR THE PRO- PHYLAXIS OF PSYCHOTIC DISEASES	)	Confirmation Number: 4939
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## **INFORMATION DISCLOSURE STATEMENT**

In accordance with the provisions of 37 C.F.R. 1.56, 1.97 and 1.98, Applicant discloses the

## following information:

Sir:

- 1. U.S. Patent No. 5,330,895 A, inventors Ramirez et al., issued July 19, 1994;
- 2. U.S. Patent No. 5,151,419 A, inventors Perenyi et al., issued September 29, 1992;
- 3. U.S. Patent No. 4,413,012 A, inventors Palfreyman et al., issued November 1, 1983;
- 4. European Patent Application No. EP 0 900 568 A2, published March 10, 1993;
- 5. United Kingdom Patent Application No. GB 2 001 060 A, published January 24, 1979;
- 6. Gerlach et al., "The Effect of L-Dopa on Young Patients with Simple Schizophrenia, Treated with Neuroleptic Drugs," <u>Psychopharmacologia</u> (Berl.), 44:105-10 (1975);
- 7. Sandor et al., "Remoxipride in the Treatment of Levodopa-Induced Psychosis," <u>J. Clin. Psychopharmacol.</u>, 16:395-9 (1996);

- 8. Fuxe et al., "Central Catecholamine Neurons, Behavior and Neuroleptic Drugs: An Analysis to Understand the Involvement of Catecholamines in Schizophrenia," <u>J. psychiat. Res.</u>, 11:151-61 (1974);
- 9. Kay et al., "L-Dopa in the Treatment of Negative Schizophrenic Symptoms: A Single-Subject Experimental Study," Int'l. J. Psychiatry in Medicine, 15(3):293-298 (1985-1986);
- 10. Brambilla et al., "Catecholaminergic Drugs in Chronic Schizophrenia," Neuropsychobiology, 5:185-200 (1979);
- 11. Scholz et al., "Treatment of Drug-induced Exogenous Psychosis in Parkinsonism with Clozapine and Fluperlapine," <u>Eur. Arch. Psychiatr. Neurol. Sci.</u>, 235:60-64 (1985);
- 12. Friedman et al., "Idiopathic Parkinson's Disease in a Chronic Schizophrenic Patient: Long-Term Treatment with Clozapine and L-Dopa," <u>Clinical Neuropharmacology</u>, 10(5):470-5 (1987);
- 13. Merello et al., "Drug-Induced Parkinsonism in Schizophrenic Patients: Motor Response and Psychiatric Changes After Acute Challenge with L-Dopa and Apomorphine," <u>Clinical Neuropharmacology</u>, 19(5):439-43 (1996);
- 14. Owens et al., "L-dopa helps positive but not negative features of neuroleptic-insensitive chronic schizophrenia," Journal of Psychopharmacology, 8(4):204-212 (1994);
- 15. Eltayb et al., "Augmentation of D2 Antagonists by Low Doses of L-Dopa in the Treatment of Schizophrenia: An Experimental Analysis," Program No. 88.10. 2003 Abstract Viewer/Itinerary Planner. Washington, DC: Society for Neuroscience, 2003. Online;
- 16. Silver et al., "The effect of augmentation with moclobemide on symptoms of schizophrenia," International Clinical Psychopharmacology, 14:193-5 (1999); and
- 17. Tollin et al., "Use of the dopamine agonists bromocriptine and cabergoline in the management of risperidone-induced hyperprolactinemia in patients with psychotic disorders," <u>J. Endocrinol. Invest.</u>, 23:765-70 (2000).

Copies of above document nos. 1-3 are not being provided with this paper since these documents are U.S. patents, for which copies are not required. Copies of above document nos. 4-17 are being provided with this paper. In addition, all of the above documents are listed on the enclosed PTO Forms PTO/SB/08A and PTO/SB/08B. Applicant respectfully requests that the Examiner consider the above-listed documents and evidence that consideration by making appropriate notations on the enclosed forms.

This submission does not represent that a search has been made or that no better prior art exists and does not constitute an admission that the above-listed documents constitute "prior art."

Applicant reserves the right to take appropriate action to establish the patentability of the disclosed invention over the above-listed documents, should the documents be applied against the claims of the present invention.

If there are any fees due in connection with the filing of this paper that are not accounted for, the Examiner is authorized to charge the fees to our Deposit Account No. 11-1755. If a fee is required for an extension of time under 37 C.F.R. 1.136 that is not accounted for already, such an extension of time is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Kriegsman & Kriegsman

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Dated: November 18, 2006

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on \_\_\_\_\_\_.

Edward M. Kriegsman

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Sul	ostitute for form 1449/PTO		Complete if Known			
ou.			Application Number	10/539,793		
I N	NFORMATION D	ISCI OSLIDE	Filing Date	December 18, 2003		
			First Named Inventor	Rudolf-Giesbert Alken		
S	TATEMENT BY		Art Unit	Unknown		
	(Use as many sheets	as necessary)	Examiner Name	Unknown		
Sheet	of		Attorney Docket Number	82444		

Examiner	Cite		Publication Date	Name of Patentee or	Pages, Columns, Lines, Where
Initials*	No.1	Number-Kind Code <sup>2 (# known)</sup>	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
		<sup>US-</sup> 5,330,895A	07-19-1994	Ramirez et al.	
		<sup>US-</sup> 5,151,419A	09-29-1992	Perenyi et al.	
		<sup>US-</sup> 4,413,012A	11-01-1983	Palfreyman et al.	
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	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages			
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T°		
	<u></u> .	EP0900568A2	03-10-1993					
		GB2001060A	01-24-1979					

Examiner	Date	
Signature	Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>8</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND** TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08B (09-06)

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Substitute for form 1449/PTO		Complete if Known			
Substitute for form 1443/FTO				Application Number	10/539,793
INFO	ORMATION	DIS	CLOSURE	Filing Date	December 18, 2003
STA	STATEMENT BY APPLICANT			First Named Inventor	Rudolf-Giesbert Alken
<i>(</i> 11				Art Unit	Unknown
(Use as many sheets as necessary)			ecessary)	Examiner Name	Unknown
Sheet		of		Attorney Docket Number	82444

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Gerlach et al., "The Effect of L-Dopa on Young Patients with Simple Schizophrenia, Treated with Neuroleptic Drugs," Psychopharmacologia (Berl.), 44:105-10 (1975)	
		Sandor et al., "Remoxipride in the Treatment of Levodopa-Induced Psychosis," J. Clin. Psychopharmacol., 16:395-9 (1996)	
		Fuxe et al., "Centr. Catecholamine Neurons, Behav. and Neuro. Drugs: An Anal. to Understand the Involvement of Catech. in Schizophrenia," J. psychiat. Res., 11:151-61 (1974)	
		Kay et al., "L-Dopa in the Treatment of Negative Schizophrenic Symptoms: A Single-Subject Experimental Study," Int'l. J. Psychiatry in Medicine, 15(3):293-8 (1985-1986)	
		Brambilla et al., "Catecholaminergic Drugs in Chronic Schizophrenia," Neuropsychobiology, 5:185-200 (1979)	
		Scholz et al., "Treatment of Drug-induced Exogenous Psychosis in Parkinsonism with Clozapine and Fluperlapine," Eur. Arch. Psychiatr. Neurol. Sci., 235:60-4 (1985)	
		Friedman et al., "Idiopathic Parkinson's Disease in a Chronic Schizophrenic Patient: Long-Term Treatment with Clozapine and L-Dopa," Clin. Neuropharmacology, 10(5):470-5, 1987	
		Merello et al., "Drug-Ind. Park. in Schiz. Patients: Motor Resp. and Psych. Changes After Acute Challenge with L-Dopa and Apomorphine," Clin. Neuropharm., 19(5):439-43, 1996	
		Owens et al., "L-dopa helps positive but not negative features of neuroleptic-insensitive chronic schizophrenia, Journal of Psychopharmacology, 8(4):204-12 (1994)	
		Silver et al., "The effect of augmentation with moclobemide on symptoms of schizophrenia," International Clinical Phsychopharmacology, 14:193-5 (1999)	

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449/PTO **Application Number** 10/539,793 Filing Date INFORMATION DISCLOSURE **December 18, 2003** STATEMENT BY APPLICANT **First Named Inventor** Rudolf-Giesbert Alken Art Unit Unknown (Use as many sheets as necessary) **Examiner Name** Unknown Attorney Docket Number Sheet 82444 of

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number(s), publisher, city and/or country where published.		
		Eltayb et al., "Augmentation of D2 Antagonists by Low Doses of L-Dopa in the Treatment of Schizophrenia: An Experimental Analysis," Program No. 88.10. 2003 Abstract	
		Viewer/Itinerary Planner. Washington, DC: Society for Neuroscience, 2003. Online	
		Tollin et al., "Use of the dopamine agonists bromocriptine and cabergoline in the management of risperidone-induced hyperprolactinemia in patients with psychotic disorders,"	
		J. Endocrinol. Invest., 23:765-70 (2000)	

Examiner	Date	
Signature	Considered	

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